CONSOLIDATED FINANCIAL REPORT [IFRS]
for the Six-Month Period Ended September 30, 2022

November 7, 2022
Eisai Co., Ltd.

Stock exchange listing: Tokyo Stock Exchange (TSE)
TSE Code: 4523
URL: https://www.eisai.com

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Expected date of quarterly report submission: November 9, 2022
Expected date of dividend payment commencement: November 18, 2022
Preparation of quarterly supplementary explanatory material: Yes
Quarterly results briefing held: Yes

(Figures are rounded to the nearest million yen)

1. Consolidated Financial Results for the Six-Month Period Ended September 30, 2022

(1) Consolidated Operating Results

(Percentage figures show year on year change)

	Revenue		Operating profit		Profit before income taxes		Profit for the period		Profit for the period attributable to owners of the parent		Comprehensive income for the period	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
Six-month period ended September 30, 2022	358,626	-1.0	5,253	-91.3	8,134	-86.7	31,802	-31.5	30,465	-33.8	102,058	103.2
Six--month period ended September 30, 2021	362,352	14.3	60,722	78.7	61,163	78.1	46,400	78.1	46,044	78.9	50,218	117.4

	Earnings per share attributable to owners of the parent (basic)	Earnings per share attributable to owners of the parent (diluted)
	(¥)	(¥)
Six-month period ended September 30, 2022	106.25	106.25
Six-month period ended September 30, 2021	160.61	160.58

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the parent	Ratio of equity attributable to owners of the parent	Equity per share attributable to owners of the parent
	(¥ million)	(¥ million)	(¥ million)	(%)	(¥)
As of September 30, 2022	1,261,278	850,703	828,128	65.7	2,887.52
As of March 31, 2022	1,239,315	771,534	748,821	60.4	2,611.82

2. Dividends

	Annual dividend per share				
	End of Q1	End of Q2	End of Q3	End of FY	Total
	(¥)	(¥)	(¥)	(¥)	(¥)
FY 2021	—	80.00	—	80.00	160.00
FY 2022	—	80.00			
FY 2022 (Forecast)			—	80.00	160.00

(Note) Revisions to the latest dividend forecast: No

3. Consolidated Financial Forecast for Fiscal 2022 (April 1, 2022 – March 31, 2023)

(Percentage figures show year on year change)

	Revenue		Operating profit		Profit before income taxes		Profit for the year		Profit for the year attributable to owners of the parent		Earnings per share attributable to owners of the parent (basic)
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥)
Fiscal Year	760,000	0.5	55,000	2.3	56,500	3.7	58,000	26.9	57,000	18.9	197.80

(Note) Revisions to the latest financial forecast: Yes

* Explanatory Notes

(1) Changes in number of significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): No

(2) Changes in accounting policies and accounting estimates:
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies other than 1): No
3) Changes in accounting estimates: No

(3) Number of shares issued (common shares):

1) Number of shares issued (including treasury shares)	As of September 30, 2022	296,566,949	As of March 31, 2022	296,566,949
2) Number of treasury shares	As of September 30, 2022	9,666,103	As of March 31, 2022	9,801,133
3) Weighted average number of shares outstanding	For the six-month period ended September 30, 2022	286,725,040	For the six-month period ended September 30, 2021	286,678,062

The Company's shares held through a trust (105,164 shares) are not included in the number of treasury shares as of the end of the period, but are included in the average number of shares outstanding as treasury shares that are deducted from the calculation of earnings per share.

* This financial report is not subject to the quarterly review procedures by independent auditors.

* Explanation concerning the appropriate use of results forecast and other special instructions:

(Caution concerning forward-looking statements)
Materials and information provided in this financial disclosure may contain "forward-looking statements" based on expectations, business goals, estimates, forecasts and assumptions that are subject to risks and uncertainties as of the publication date of these materials. Accordingly, actual outcomes and results may differ materially from these statements depending on a number of important factors. Please refer to the pages 10-11 for details with regard to the assumptions and other related matters concerning the consolidated financial forecast.

(Methods for obtaining supplementary materials and content of financial results disclosure meeting)
Supplementary materials are attached to this financial report. The Company plans to hold a financial results disclosure meeting for institutional investors and securities analysts on Monday, November 7, 2022. The handouts from the disclosure meeting will be made available on the Company's website after the event.

Supplemental Materials: Table of Contents

1. Qualitative Information regarding Financial Results for the Period

(1) Operating Results

[Revenue and Profit]

○ Eisai Co., Ltd. (“the Company”) and its affiliates (collectively referred to as “the Group”) recorded the following consolidated financial results for the six-month period ended September 30, 2022.

(¥billion)

	Six-month period ended September 30, 2021	**Six-month period ended September 30, 2022**	Year on year change (%)
Revenue	362.4	**358.6**	99.0
Cost of sales	79.9	**92.5**	115.9
Gross profit	282.5	**266.1**	94.2
Selling, general and administrative expenses	154.7	**180.4**	116.6
Research and development expenses	79.9	**81.5**	102.0
Operating profit	60.7	**5.3**	8.7
Profit before income taxes	61.2	**8.1**	13.3
Income taxes	14.8	**(23.7)**	—
Profit for the period	46.4	**31.8**	68.5
Profit for the period attributable to owners of the parent	46.0	**30.5**	66.2

○ While global brands such as anticancer agent Lenvima continued to grow, revenue decreased due to the impact mainly caused by the recording of an upfront payment (¥49.6 billion) from Bristol Myers Squibb (the U.S.) under strategic collaboration for antibody drug conjugate MORAb-202 in the same period of the previous fiscal year. Revenue of pharmaceutical business increased significantly to ¥352.6 billion (117.8% year on year).

○ Regarding revenue from global brands, revenue for Lenvima, anticancer agent Halaven, antiepileptic agent Fycompa and insomnia treatment Dayvigo was ¥128.2 billion (139.6% year on year), ¥21.4 billion (107.5% year on year), ¥20.1 billion (132.8% year on year) and ¥13.6 billion (214.4% year on year), respectively.

○ Selling, general and administrative expenses increased significantly mainly due to the depreciation of the Japanese yen, in addition to increase in shared profit paid to Merck & Co., Inc., Rahway, NJ, USA following Lenvima’s revenue growth, despite decrease in expenses related to Alzheimer’s disease (AD) treatment ADUHELM (aducanumab).

○ While efficiency increased through the partnership model, research and development expenses increased due to continuous resource investment in important projects such as anti-amyloid beta protofibril antibody lecanemab and Lenvima, as well as the depreciation of yen.

○ As a result of the above, although operating profit decreased, segment profit of pharmaceutical business increased significantly achieving ¥173.0 billion (128.4% year on year).

○ Profit for the period increased compared to profit before income taxes following recording of a credit of income taxes due to the Company's recognition of losses on transferring of investments in subsidiaries for tax purposes following a repayment of paid-in capital from a consolidated U.S. subsidiary to the Company in order to collect capital from the consolidated U.S. subsidiary as part of the Group's capital policy to optimize the global allocation of cash in the Group.

[Performance by Segment]

(Revenue for each segment indicates revenue from external customers)

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia and Oceania), Asia and Latin America (primarily South Korea, Taiwan, India, ASEAN, Central and South America), and OTC and others (Japan). Effective from this fiscal year, Hong Kong has been changed from the "Asia and Latin America" segment to the "China" segment. Also, as the co-development and co-promotion agreements with Biogen Inc. (the U.S., hereinafter "Biogen") regarding ADUHELM were amended in March 2022, expenses related to ADUHELM (selling, general and administrative expenses) which the Company should share have been included in the "Group headquarters' management costs and other expenses". In addition, gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses" and upfront payments and other factors received as the consideration of the license grant have been included in "other business". The year on year changes in the segment performance for this report are based on this new segmentation.

<Japan pharmaceutical business>

○ Total revenue came to ¥110.6 billion (106.3 % year on year), with a segment profit of ¥37.7 billion (115.2% year on year).

○ Regarding revenue by products, from neurology products, revenue for Dayvigo came to ¥11.1 billion (235.5% year on year), achieving significant growth. Revenue for Fycompa came to ¥3.0 billion (117.6% year on year) achieving growth. Among oncology products, revenue for Lenvima came to ¥6.9 billion (134.3% year on year) achieving significant growth due to impact of additional indications. Revenue for Halaven came to ¥4.3 billion (104.3% year on year). Fully human anti-TNF-α monoclonal antibody Humira earned revenue of ¥24.7 billion (99.4% year on year). Revenue for chronic constipation treatment Goofice came to ¥3.3 billion (113.7% year on year). Revenue for Jyseleca, a JAK (Janus kinase) inhibitor, came to ¥3.0 billion (¥0.3 billion in the same period of the previous fiscal year) achieving significant growth.

<Americas pharmaceutical business>

○ Total revenue came to ¥106.4 billion (141.2% year on year), with a segment profit of ¥64.4 billion (154.1% year on year).

○ Regarding revenue by products, from neurology products, revenue for Fycompa and Dayvigo both achieved significant growth coming to ¥9.4 billion (135.1% year on year) and ¥2.3 billion (145.4% year on year), respectively. Among oncology products, Lenvima earned ¥80.2 billion (156.3% year on year) achieving significant growth due to impact of additional indications. Revenue for Halaven came to ¥7.7 billion (112.0% year on year).

<China pharmaceutical business>

○ Revenue totaled ¥63.3 billion (114.5% year on year), with a segment profit of ¥35.3 billion (112.9% year on year).

○ Regarding revenue by products, revenue for Lenvima came to ¥20.7 billion (97.4% year on year) mainly due to impact of generic pharmaceuticals. Revenue for peripheral neuropathy treatment Methycobal achieved significant growth coming to ¥8.4 billion (127.2% year on year). Proton pump inhibitor Pariet earned ¥4.9 billion (106.1% year on year). Liver disease and anti-allergy agents Stronger Neo-Minophagen C and Glycyron Tablets together recorded ¥4.5 billion (84.2% year on year).

<EMEA pharmaceutical business>

○ Revenue totaled ¥35.0 billion (124.7% year on year). A segment profit totaled ¥20.5 billion (134.2% year on year).

○ Regarding revenue by products from neurology products, revenue for Fycompa came to ¥5.5 billion (126.9% year on year) achieving significant growth. Among oncology products, revenue for Lenvima/Kisplyx achieved significant growth recording ¥15.0 billion (150.1% year on year). Revenue for Halaven came to ¥6.8 billion (105.4% year on year).

<Asia and Latin America pharmaceutical business>

○ Revenue totaled ¥24.8 billion (100.6% year on year), with a segment profit of ¥11.8 billion (109.6% year on year).

○ Regarding revenue by products, Lenvima achieved significant growth, recording revenue of ¥5.4 billion (131.1% year on year). Revenue for Aricept, a treatment for Alzheimer's disease dementia, came to ¥6.7 billion (112.7% year on year).

○ Dayvigo was launched in India and Singapore in April 2022, and in Taiwan in May of the same year.

< OTC and others business>

○ Revenue totaled ¥12.6 billion (103.9% year on year), with a segment profit of ¥3.3 billion (113.1% year on year).

○ Revenue for Chocola BB Group came to ¥7.7 billion (106.2% year on year).

(2) Financial Position

[Assets, Liabilities, and Equity]

- ○ Total assets as of the end of the period amounted to ¥1,261.3 billion (up ¥22.0 billion from the end of the previous fiscal year). Assets of overseas consolidated subsidiaries increased due to the depreciation of the Japanese yen. In addition, deferred tax assets of the Company increased.
- ○ Total liabilities as of the end of the period amounted to ¥410.6 billion (down ¥57.2 billion from the end of the previous fiscal year). This was mainly due to a decrease in accounts payable-other to partners.
- ○ Total equity as of the end of the period amounted to ¥850.7 billion (up ¥79.2 billion from the end of the previous fiscal year). Exchange differences on translation of foreign operations increased following the depreciation of yen.
- ○ As a result of the above, the ratio of equity attributable to owners of the parent was 65.7% (up 5.2 percentage points from the end of the previous fiscal year).

[Cash Flows]

- ○ Net cash from operating activities amounted to an outflow of ¥18.8 billion (inflow of ¥67.9 billion in the same period of the previous fiscal year). While accounts receivable-trade were collected, working capital increased mainly due to payment of accounts payable-other to partners.
- ○ Net cash used in investing activities amounted to an outflow of ¥16.4 billion (up ¥9.0 billion from the same period of the previous fiscal year). There were capital expenditures following the expansion of research facilities and production facilities.
- ○ Net cash used in financing activities amounted to an outflow of ¥27.8 billion (down ¥0.1 billion from the same period of previous fiscal year), mainly due to dividends paid.
- ○ As a result of the above, cash and cash equivalents as of the end of the period stood at ¥264.5 billion (down ¥45.1 billion from the end of the previous fiscal year). Free cash flow (cash flow from operating activities less capital expenditures) for the period was an outflow of ¥35.3 billion.

(3) Research & Development Pipeline, Alliances, and Other Events

[Status of Ongoing Research & Development Pipelines]

- ○ Anticancer agent Lenvima (product name for renal cell carcinoma indication in Europe: Kisplyx, lenvatinib, jointly developed with Merck & Co., Inc., Rahway, NJ, USA)
  - ✧ Approved for use in the treatment of thyroid cancer (monotherapy) in over 80 countries including Japan, the United States, in Europe, China and in Asia.
  - ✧ Approved for use in the treatment of hepatocellular carcinoma (first-line, monotherapy) in over 80 countries including Japan, the United States, in Europe, China and in Asia.
  - ✧ Approved for use in the treatment of unresectable thymic carcinoma (monotherapy) in Japan.
  - ✧ Approved in combination with everolimus for use in the treatment of renal cell carcinoma (second-line) in over 65 countries, including the United States and in Europe.
  - ✧ Approved in combination with the anti-PD-1 therapy pembrolizumab from Merck & Co., Inc., Rahway, NJ, USA for use in the treatment of renal cell carcinoma (first-line) in over

40 countries including Japan, the United States, in Europe and in Asia.

- ✧ The agent obtained approval (including conditional approval) in combination with pembrolizumab for use in the treatment of endometrial carcinoma (following prior systemic therapy) in over 45 countries including Japan, the United States, in Europe and in Asia.
- ✧ In August 2022, a Phase III trial investigating the combination therapy with pembrolizumab versus Lenvima monotherapy as a first-line treatment in patients with hepatocellular carcinoma did not meet its dual primary endpoints of overall survival (OS) and progression-free survival (PFS). There were trends toward improvement in OS and PFS for patients who received the combination therapy versus Lenvima monotherapy; however, these results did not meet statistical significance per the pre-specified statistical plan. The median OS of the Lenvima monotherapy arm in the trial was longer than that observed in previously reported clinical trials evaluating Lenvima monotherapy in hepatocellular carcinoma. The safety profile of Lenvima plus pembrolizumab was consistent with previously reported data on the combination.
- ✧ Regarding studies of the agent in combination with pembrolizumab, respective Phase III studies for endometrial carcinoma (first-line), melanoma (first-line), nonsquamous non-small cell lung cancer (first-line, in combination with chemotherapy), non-small cell lung cancer (second-line), head and neck cancer (first-line), hepatocellular carcinoma (first-line, in combination with transcatheter arterial chemoembolization), esophageal carcinoma (first-line, in combination with chemotherapy), gastric cancer (first-line, in combination with chemotherapy), and colorectal cancer (non-MSI-H / mismatch repair proficient [pMMR], third-line) are underway in the United States, Europe and other countries.
- ✧ Regarding studies of the agent in combination with pembrolizumab, Phase II studies for melanoma (second-line) and head and neck cancer (second-line), as well as a Phase II basket trial in multiple cancer types are underway in the United States, Europe and other countries.

○ Anticancer agent Halaven (eribulin)

- ✧ Approved for use in the treatment of breast cancer in over 80 countries including Japan, the United States, in Europe, China and in Asia.
- ✧ Approved for use in the treatment of liposarcoma (soft tissue sarcoma in Japan) in over 80 countries, including Japan, the United States, in Europe and in Asia.
- ✧ A Phase I/II study for the combination therapy of the liposomal formulation of Halaven and anti-PD-1 antibody nivolumab of Ono Pharmaceutical Co., Ltd. (Osaka, Japan) is underway in Japan.

○ Antiepileptic agent Fycompa (perampanel)

- ✧ Approved in over 70 countries including Japan, the United States, in Europe, China and in Asia, as an adjunctive therapy for use in the treatment of partial-onset seizures in patients with epilepsy 12 years of age and older. The agent was approved for monotherapy and adjunctive use in the treatment of partial-onset seizures in patients with epilepsy 4 years of age and older in Japan, the United States and China. The agent

was approved for adjunctive use in the treatment of partial-onset seizures in patients with epilepsy 4 years of age and older in Europe.

- ✧ Approved in over 70 countries including Japan, the United States, in Europe and in Asia, as an adjunctive therapy for use in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. The agent was approved an adjunctive therapy for primary generalized tonic-clonic seizures in pediatric patients with epilepsy 7 years of age and older in Europe.
- ✧ In August 2022, an application was filed in Japan seeking approval for an injection formulation as a new route of administration.
- ✧ A Phase III study for Lennox-Gastaut syndrome is underway in Japan, the United States and Europe.

○ Orexin receptor antagonist Dayvigo (lemborexant)

- ✧ The agent was approved for the treatment of insomnia in more than 10 countries including Japan, the United States and countries in Asia.
- ✧ A Phase III study for insomnia is underway in China.
- ✧ A Phase II study for irregular sleep-wake rhythm disorder associated with Alzheimer's disease dementia has been finished and consideration for future development is underway.

○ Anti-amyloid beta protofibril antibody lecanemab (development code: BAN2401, jointly developed with Biogen)

- ✧ In July 2022, a Biologics License Application (BLA) under the accelerated approval pathway for the treatment of early AD (mild cognitive impairment due to AD or mild AD) based on Study 201 (Phase II study) was accepted by the U.S. Food and Drug Administration (FDA) in the United States. This application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of January 6, 2023. The agent was granted Breakthrough Therapy designation and Fast Track designation for AD treatment in the United States.
- ✧ In September 2022, the primary endpoint and all key secondary endpoints of the Clarity AD (Phase III) study in early-stage AD were met with highly statistically significant results. The amyloid-related imaging abnormality (ARIA) expression profile was within expectations. Based on the results of this study, Eisai aims to file for traditional approval in the United States and marketing authorization applications in Japan and Europe in FY2022. This study is underway in China.
- ✧ A submission of application data to the Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system has been initiated in Japan.
- ✧ AHEAD 3-45 (Phase III study) for preclinical (asymptomatic) AD is underway in countries including Japan, the United States and in Europe. In this study, the agent has been selected by the Alzheimer's Clinical Trials Consortium (ACTC) as a treatment to be evaluated.
- ✧ Development of subcutaneous dosing is underway with aim of enhancing benefit.

○ In May 2022, ultrahigh-dose mecobalamin received orphan drug designation with a prospective indication for delaying the progression of disease and functional impairment of amyotrophic lateral sclerosis (ALS), by the Ministry of Health, Labour and Welfare in Japan. With the result of an investigator-initiated Phase III trial, Eisai plans to submit a new drug application during the fiscal year 2023.

○ In October 2022, Eisai received notification from Japan's Ministry of Health, Labour and Welfare that Aricept (donepezil hydrochloride), a treatment for Alzheimer's disease and dementia with Lewy bodies, was granted continued approval with a partial change to label regarding dosing and administration. In response, Eisai plans to promptly submit an application for the change. The indication for dementia with Lewy bodies remains unchanged.

○ In November 2022, Eisai received notification from Japan's Ministry of Health, Labour and Welfare that the "all-case study" specified post-marketing observational study condition required at the time of approval of anti-epileptic agent Inovelon (rufinamide) as an adjunctive therapy to other antiepileptic drugs for Lennox-Gastaut syndrome, had been lifted in Japan.

○ A Phase II part of Phase I/II clinical trial of E7386 in combination with pembrolizumab for solid tumors has been initiated and is underway in Japan, the United States and Europe.

○ A Phase III REMAP-COVID study of eritoran, a Toll-Like Receptor (TLR) 4 antagonist, for suppression for increasing of severity of COVID-19 in Japan and the United States was discontinued.

○ Development of E2730 (a treatment for neurological diseases) for epilepsy at a Phase II stage in the United States has been finished.

[Major Alliances, Agreements and Other Events]

○ In April 2022, Centers for Medicare and Medicaid Services (CMS) announced the finalized National Coverage Determination (NCD) for monoclonal antibodies directed against amyloid for the treatment of AD and decided to cover treatments receiving accelerated approval based upon evidence of efficacy from a change in a surrogate endpoint only if patients are enrolled in CMS-approved randomized controlled clinical trials. At the same time, CMS has committed to quickly reconsider the NCD for treatments which have obtained full approval with quality evidence on clinical benefit.

○ In May 2022, Eisai established pharmaceutical sales company EISAI PHARMACEUTICALS AFRICA (PTY) LTD as its subsidiary in Republic of South Africa.

○ In May 2022, EA Pharma Co., Ltd. (Tokyo, hereinafter EA Pharma) launched a high dose formulation which is a new dosage form of MOVICOL, a chronic constipation treatment, in Japan. Eisai will co-promote the product with EA Pharma.

○ In June 2022, Eisai announced that a brain health check utilizing "NouKNOW", a digital tool (non-medical device) for self-assessment of brain performance (brain health) developed by Eisai, will be promoted as part of the FY2022 dementia examination project conducted by Bunkyo City, Tokyo.

○ In June 2022, Eisai signed the Kigali Declaration on neglected tropical diseases (NTDs) and expressed its continued support for the elimination of NTDs towards the achievement of the road map for NTDs 2021-2030 launched by the World Health Organization (WHO).

○ In June 2022, Eisai entered into a business alliance agreement with E.design Insurance Co., Ltd. (Tokyo), a direct non-life insurance company of the Tokio Marine Group, aiming to realize a society where people can safely enjoy driving for a longer period of their lives under the theme of “Improving Brain Health for Safe Driving”.

○ In July 2022, partnership with Pfizer Inc. (the U.S.) for Lyrica, a pain treatment, was ended due to expiration of co-promotion agreement in Japan.

○ In July 2022, under the concept of Deep Human Biology Learning (DHBL), Eisai transitioned to a new DHBL drug discovery that is based on Eisai’s R&D with creating synergy of “C&I” (Collaboration & Incubation) and “A&I” (Academia/ Industry Alliance). The functions for clinical development and establishment of a solid launch structure for next-generation AD treatments and dementia-related disease treatments were reorganized as Alzheimer's Disease and Brain Health (ADBH) under the Global AD Officer. Eisai plans to integrate H3 Biomedicine Inc., an R&D subsidiary in the United States, into its parent company, Eisai Inc. (the U.S.) in this year.

○ In August 2022, Eisai entered into a capital and business alliance agreement with LIFENET INSURANCE COMPANY (Tokyo), aimed at building an ecosystem to reduce the burden of medical and nursing care.

○ In August 2022, Eisai entered into a joint research agreement with Honda Motor Co., Ltd. (Tokyo), Oita University and the Usuki City Medical Association to verify the relationship between changes in cognitive function and daily physical condition, and driving ability, with the aim of realizing a society in which elderly drivers can maintain their safety and health.

○ In August 2022, U.S. subsidiary Eisai Inc. entered into a memorandum of understanding with C_2N Diagnostics (the U.S.) to build awareness and real-world evidence for blood-based assays in the diagnosis of people living with cognitive impairment in clinical practice in the United States outside of clinical trial settings.

○ In September 2022, Eisai’s subsidiary Sunplanet Co., Ltd. (Tokyo) was made a wholly owned subsidiary through a share exchange.

○ In September 2022, nippon medac Co., Ltd. (Tokyo), a subsidiary of medac GmbH (Germany) obtained an approval in Japan for the indication of the anti-rheumatic agent Metoject Subcutaneous Injection (methotrexate) for the treatment of rheumatoid arthritis. Based on the license agreement with medac GmbH, Eisai will be responsible for product distribution in Japan.

○ In October 2022, Eisai completed construction of the new injection/research building at the Kawashima Industrial Park located in Gifu Prefecture, Japan, with aim of strengthening its injectable drug formulation development research function and drug delivery system development function.

○ In November 2022, Eisai (Thailand) Marketing Co. Ltd., Eisai’s Thai sales subsidiary, made an agreement with Thai Life Insurance Public Company Limited, a leading life insurance company in Thailand, to collaborate in supporting access to treatments for dementia, including Alzheimer's disease, in Thailand.

○ In November 2022, Eisai entered into an agreement to divest its rights for muscle relaxant Myonal (eperisone hydrochloride) and vertigo and equilibrium disturbance treatment Merislon (betahistine mesilate) in 9 countries/regions in Asia (excluding Japan, China, South Korea and others) to a subsidiary of DKSH Holding Ltd. (Switzerland).

(4) Information on Outlook for the Future including Financial Forecast (April 1, 2022 – March 31, 2023)

[Consolidated Financial Forecast]

○ The consolidated financial forecast for fiscal 2022 (April 1, 2022 – March 31, 2023) have been revised from the forecasts previously announced on June 8, 2022, as follows:

	Revised forecast		Previous forecast		Increase/ Decrease	Rate of change
	(A)	YOY	(B)	YOY	(A-B)	
Revenue	¥760.0 billion	100.5%	¥700.0 billion	92.6%	up ¥60.0 billion	up 8.6%
Operating profit	¥55.0 billion	102.3%	¥55.0 billion	102.3%	—	—
Profit before income taxes	¥56.5 billion	103.7%	¥56.5 billion	103.7%	—	—
Profit for the year	¥58.0 billion	126.9%	¥58.0 billion	126.9%	—	—
Profit for the year attributable to owners of the parent	¥57.0 billion	118.9%	¥57.0 billion	118.9%	—	—
Earnings per share attributable to owners of the parent (basic)	¥197.80	118.3%	¥197.80	118.3%	—	—

(Assumptions for third and fourth quarters: 1 USD = ¥143.0, 1 EUR = ¥142.0, 1 GBP = ¥162.0, 1 RMB = ¥20.4)

<Revenue and profit>

○ Revenue is estimated to be ¥760.0 billion, up ¥60.0 billion from the previously announced forecasts, based on consideration of latest exchange trends and strong growth of global brands, including Lenvima.

○ While gross profit increases, operating profit remains unchanged from the previous forecast considering continuous resource investment in research and development in AD areas, including lecanemab, and oncology areas while pursuing cost efficiency, as well as increase in shared profit paid to Merck & Co., Inc., Rahway, NJ, USA following Lenvima's revenue growth.

○ Profit for the year remains unchanged from the previous forecast.

○ The annual dividend forecast remains unchanged at ¥160 per share (the same amount as the previous fiscal year).

[Forecasts and Risk Factors]

○ The materials and information provided in this announcement include current forecasts, targets, evaluations, estimates, assumptions that are accompanied by risks, and other matters that are based on uncertain factors. Accordingly, it is possible that actual results will deviate significantly from forecasts, etc., due to changes to a variety of factors. These risks and uncertainties include general industry and market conditions, fluctuation of interest rates and currency exchange rates, and other aspects of economic conditions in Japan and internationally.

○ Risks and uncertainties that could cause significant fluctuations in the results of the Group or have a material effect on investment decisions are as follows. However, these do not cover all of the risks and uncertainties faced by the Group, and it is possible that they will be affected in the future by other factors that cannot be foreseen, or are not deemed to be important, at this point in time.

○ These are judgments as of the time of the announcement, and statements in the text regarding the future are not guarantees that they will occur or be achieved.

○ Risks factors include risks related to management based on the Corporate Concept, risks related to maximization of the value of next-generation AD treatments, risks related to maximization of the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to uncertainties in new drug development, risks related to occurrences of side effects, risks related to product quality and stable supply, risks related to intellectual property, risks related to litigations, risks related to data reliability, risks related to trends to contain medical costs, risks related to succession, risks related to acquiring and developing human resources, risks related to information security, risks related to COVID-19, risks related to climate change, risks related to impairment of goodwill and intangible assets.

○ For further details on the above-mentioned risks, please refer to the “Risk Factors” section of the Annual Securities Report.

(5) Basic Policy on Profit Appropriation and Interim Dividend for the End of the Second Quarter of Fiscal 2022

The Company pays dividends to all shareholders in a sustainable and stable way based on factors such as a healthy balance sheet and comprehensive consideration of the consolidated financial results, Dividends on Equity (DOE) and free cash flow, as well as taking into consideration the signaling effect. Because DOE indicates the ratio of dividends to consolidated net assets, the Group has positioned it as an indicator that reflects balance sheet management, and, consequently, capital policy. Acquisition of treasury stock will be carried out appropriately after factors such as the market environment and capital efficiency are taken into account. The Group uses the ratio of equity attributable to owners of the parent and net debt equity ratio as indicators to measure a healthy balance sheet.

At the Company, the dividend payments are determined by a resolution of the Board of Directors as specified in the Company’s Articles of Incorporation. The Company has set the interim dividend for the end of the second quarter of FY 2022 at ¥80 per share (the same amount as in FY 2021) as previously projected.

2. Condensed Interim Consolidated Financial Statements and Major Notes
(1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	For the six-month period ended September 30, 2022	For the six-month period ended September 30, 2021
Revenue	358,626	362,352
Cost of sales	(92,536)	(79,871)
Gross profit	266,089	282,481
Selling, general and administrative expenses	(180,389)	(154,681)
Research and development expenses	(81,517)	(79,917)
Other income	3,029	13,668
Other expenses	(1,960)	(829)
Operating profit	5,253	60,722
Financial income	3,736	1,219
Financial costs	(855)	(778)
Profit before income taxes	8,134	61,163
Income taxes	23,668	(14,763)
Profit for the period	31,802	46,400
Profit for the period attributable to		
Owners of the parent	30,465	46,044
Non-controlling interests	1,337	356
Earnings per share		
Basic (yen)	106.25	160.61
Diluted (yen)	106.25	160.58

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	For the six-month period ended September 30, 2022	For the six-month period ended September 30, 2021
Profit for the period	31,802	46,400
Other comprehensive income (loss)		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income (loss)	4,054	(17)
Subtotal	4,054	(17)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations (loss)	66,173	3,796
Cash flow hedges	29	39
Subtotal	66,202	3,835
Total other comprehensive income (loss), net of tax	70,256	3,817
Comprehensive income (loss) for the period	102,058	50,218
Comprehensive income (loss) for the period attributable to		
Owners of the parent	100,702	49,875
Non-controlling interests	1,356	342

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of September 30, 2022	As of March 31, 2022
Assets		
Non-current assets		
Property, plant and equipment	175,688	169,926
Goodwill	226,206	191,758
Intangible assets	93,772	95,451
Other financial assets	48,199	44,033
Other assets	20,548	20,919
Deferred tax assets	111,488	76,622
Total non-current assets	675,900	598,709
Current assets		
Inventories	114,410	99,008
Trade and other receivables	178,091	207,950
Other financial assets	1,000	432
Other assets	27,350	23,584
Cash and cash equivalents	264,527	309,633
Total current assets	585,379	640,606
Total assets	1,261,278	1,239,315

(Millions of yen)

	As of September 30, 2022	As of March 31, 2022
Equity		
Equity attributable to owners of the parent		
Share capital	44,986	44,986
Capital surplus	78,813	77,605
Treasury shares	(33,623)	(33,936)
Retained earnings	518,186	506,583
Other components of equity	219,766	153,584
Total equity attributable to owners of the parent	828,128	748,821
Non-controlling interests	22,576	22,712
Total equity	850,703	771,534
Liabilities		
Non-current liabilities		
Borrowings	84,912	94,893
Other financial liabilities	39,109	39,213
Provisions	1,531	1,473
Other liabilities	17,481	18,386
Deferred tax liabilities	1,005	483
Total non-current liabilities	144,039	154,449
Current liabilities		
Borrowings	9,998	—
Trade and other payables	76,827	108,065
Other financial liabilities	40,588	40,865
Income taxes payable	5,458	6,877
Provisions	25,352	17,949
Other liabilities	108,314	139,576
Total current liabilities	266,536	313,333
Total liabilities	410,575	467,782
Total equity and liabilities	1,261,278	1,239,315

(4) Condensed Interim Consolidated Statement of Changes in Equity

For the six-month period ended September 30, 2022

(Millions of yen)

	Equity attributable to owners of the parent				
					Other components of equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Financial assets measured at fair value through other comprehensive income (loss)
As of April 1, 2022	44,986	77,605	(33,936)	506,583	—
Profit for the period	—	—	—	30,465	—
Total other comprehensive income (loss)	—	—	—	—	4,054
Comprehensive income (loss) for the period	—	—	—	30,465	4,054
Dividends	—	—	—	(22,941)	—
Share-based payments	—	(27)	—	—	—
Acquisition of treasury shares	—	—	(5)	—	—
Disposal of treasury shares	—	43	73	—	—
Changes in equity in existing subsidiaries	—	1,192	244	—	—
Reclassification	—	—	—	4,054	(4,054)
Other changes	—	—	—	25	—
Total transactions with owners (loss)	—	1,208	312	(18,862)	(4,054)
As of September 30, 2022	44,986	78,813	(33,623)	518,186	—

	Equity attributable to owners of the parent					
	Other components of equity					
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity	Total equity attributable to owners of the parent	Non-controlling interests	Total equity
As of April 1, 2022	153,584	—	153,584	748,821	22,712	771,534
Profit for the period	—	—	—	30,465	1,337	31,802
Total other comprehensive income (loss)	66,153	29	70,237	70,237	19	70,256
Comprehensive income (loss) for the period	66,153	29	70,237	100,702	1,356	102,058
Dividends	—	—	—	(22,941)	(44)	(22,985)
Share-based payments	—	—	—	(27)	—	(27)
Acquisition of treasury shares	—	—	—	(5)	—	(5)
Disposal of treasury shares	—	—	—	116	—	116
Changes in equity in existing subsidiaries	—	—	—	1,437	(1,449)	(13)
Reclassification	—	—	(4,054)	—	—	—
Other changes	—	—	—	25	—	25
Total transactions with owners (loss)	—	—	(4,054)	(21,395)	(1,493)	(22,888)
As of September 30, 2022	219,737	29	219,766	828,128	22,576	850,703

For the six-month period ended September 30, 2021

(Millions of yen)

	Equity attributable to owners of the parent				
					Other components of equity
	Share capital	Capital surplus	Treasury Shares	Retained earnings	Financial assets measured at fair value through other comprehensive income (loss)
As of April 1, 2021	44,986	77,628	(34,049)	506,403	—
Profit for the period	—	—	—	46,044	—
Total other comprehensive income (loss)	—	—	—	—	(17)
Comprehensive income (loss) for the period	—	—	—	46,044	(17)
Dividends	—	—	—	(22,938)	—
Share-based payments	—	(19)	—	—	—
Acquisition of treasury shares	—	—	(21)	—	—
Disposal of treasury shares	—	9	88	—	—
Reclassification	—	—	—	(17)	17
Other changes	—	0	—	8	—
Total transactions with owners (loss)	—	(9)	67	(22,948)	17
As of September 30, 2021	44,986	77,619	(33,982)	529,499	—

	Equity attributable to owners of the parent					
	Other components of equity					
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity	Total equity attributable to owners of the parent	Non-controlling interests	Total equity
As of April 1, 2021	106,702	(69)	106,633	701,601	24,759	726,360
Profit for the period	—	—	—	46,044	356	46,400
Total other comprehensive income (loss)	3,810	39	3,832	3,832	(14)	3,817
Comprehensive income (loss) for the period	3,810	39	3,832	49,875	342	50,218
Dividends	—	—	—	(22,938)	(101)	(23,039)
Share-based payments	—	—	—	(19)	—	(19)
Acquisition of treasury shares	—	—	—	(21)	—	(21)
Disposal of treasury shares	—	—	—	98	—	98
Reclassification	—	—	17	—	—	—
Other changes	—	—	—	8	(1)	7
Total transactions with owners (loss)	—	—	17	(22,873)	(102)	(22,975)
As of September 30, 2021	110,512	(30)	110,482	728,604	25,000	753,603

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	For the six-month period ended September 30, 2022	For the six-month period ended September 30, 2021
Operating activities		
Profit before income taxes	8,134	61,163
Depreciation and amortization	19,693	18,987
Impairment losses	272	249
(Increase) decrease in working capital	(26,595)	3,996
Interest and dividends received	1,310	1,002
Interest paid	(710)	(587)
Income taxes paid	(12,962)	(4,762)
Income taxes refund	—	2,564
Other	(7,987)	(14,696)
Net cash from (used in) operating activities	(18,846)	67,916
Investing activities		
Purchases of property, plant and equipment	(14,171)	(18,255)
Purchases of intangible assets	(6,549)	(3,191)
Proceeds from sale of property, plant and equipment and intangible assets	347	13,293
Purchases of financial assets	(1,904)	(1,529)
Proceeds from sale and redemption of financial assets	5,850	2,262
Payments of time deposits exceeding three months	(0)	(0)
Proceeds from redemption of time deposits exceeding three months	0	0
Other	18	(35)
Net cash from (used in) investing activities	(16,408)	(7,454)
Financing activities		
Repayments of long-term borrowings	(2)	—
Repayments of lease liabilities	(4,882)	(5,199)
Dividends paid	(22,941)	(22,938)
Other	26	192
Net cash from (used in) financing activities	(27,800)	(27,946)
Effect of exchange rate change on cash and cash equivalents	17,948	1,745
Net increase (decrease) in cash and cash equivalents	(45,106)	34,262
Cash and cash equivalents at beginning of period	309,633	248,740
Cash and cash equivalents at end of period	264,527	283,002

(6) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern)

Not applicable

(Changes in Accounting Policies)

With the exception of the following, all significant accounting policies that are applied to these condensed interim consolidated financial statements for this period are the same as those that were applied to the consolidated financial statements for the previous fiscal year. None of the following accounting standards and interpretations applied by the Group has any major impact on the condensed interim consolidated financial statements for this period.

Accounting standards and interpretations		Mandatory application (Date of commencement)	To be applied by the Group	Description
IAS 16	Property, Plant and Equipment	January 1, 2022	Fiscal year ending March 31, 2023	Amendments to proceeds before intended use of property, plant and equipment
IAS 37	Provisions, Contingent Liabilities and Contingent Assets	January 1, 2022	Fiscal year ending March 31, 2023	Clarifying cost of fulfilling onerous contracts
IFRS 3	Business Combinations	January 1, 2022	Fiscal year ending March 31, 2023	Amendments to reference to the Conceptual Framework

The Group changed its accounting policies related to "Configuration or customization costs in a cloud computing agreement (related to IAS 38)" in the previous fiscal year. The changes in accounting policies are applied retroactively. The condensed interim consolidated financial statements for the six-month period ended September 30, 2021 have been restated to reflect the changes. As a result of applying the changes, compared to the amounts prior to the retroactive application, in the condensed interim consolidated statement of income for the six-month period ended September 30, 2021, selling, general and administrative expenses increased by ¥198 million. Research and development expenses decreased by ¥14 million. Both operating profit and profit before income taxes decreased by ¥184 million. Profit for the period decreased by ¥142 million.

(Segment Information)

Reporting segments are units for which the Group can obtain independent financial information and for which top management undertakes periodic reviews in order to determine the allocation of management resources and evaluate performance.

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia and Oceania), Asia and Latin America (primarily South Korea, Taiwan, India, ASEAN, Central and South America), and OTC and others (Japan).

Hong Kong has been changed from the "Asia and Latin America pharmaceutical business" to the "China pharmaceutical business" since April 1, 2022. This change has been reflected on "Revenue" and "Segment profit (loss)" for the fiscal year ended March 31, 2022 provided in Segment Information.

As the co-development and co-promotion agreements on Alzheimer's disease treatment ADUHELM (aducanumab) with Biogen Inc. (the U.S.) were amended in March 2022, expenses related to ADUHELM (selling, general and administrative expenses) which the Company should share based on the agreements have been included in the "Group headquarters' management costs and other expenses" since April 1, 2022. In addition to that, in order to more accurately reflect the condition of the business, gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses" and upfront payments and other factors received as the consideration of the license grant have been included in "Other business". For the fiscal year ended March 31, 2022, the above changes have been reflected in Segment Information.

(Millions of yen)

	For the six-month period ended September 30, 2022		For the six-month period ended September 30, 2021	
	Revenue	Segment profit (loss)	Revenue	Segment profit (loss)
Pharmaceutical business				
Japan	110,556	37,689	103,991	32,712
Americas	106,390	64,441	75,355	41,806
China	63,277	35,331	55,263	31,283
EMEA	34,952	20,501	28,029	15,275
Asia and Latin America	24,772	11,807	24,616	10,774
OTC and others	12,623	3,252	12,149	2,875
Reporting segment total	352,570	173,021	299,403	134,726
Other business (Note 1)	6,055	1,266	62,949	58,987
Total	358,626	174,287	362,352	193,713
R&D expenses (Note 2)	—	(81,517)	—	(79,917)
Group headquarters' management costs and other expenses (Note 3)	—	(87,517)	—	(53,074)
Operating profit in the condensed interim consolidated statement of income	—	5,253	—	60,722

(Note 1) “Other business” mainly includes the license revenue and pharmaceutical ingredient business of the parent company and other factors. For the six-month period ended September 30, 2021, an upfront payment of ¥49,649 million from Bristol Myers Squibb (the U.S.) under the strategic collaboration for antibody drug conjugate MORAb-202 was included in “Revenue” and “Segment profit (loss).”

(Note 2) “R&D expenses” are not allocated to any particular segment as the Group manages such expenses on a global basis.

(Note 3) “Group headquarters’ management costs and other expenses” are the costs and expenses covering Group-wide operations which include the amount of other income and expenses, and the amount of profits and expenses shared under strategic collaborations with partners. For the six-month period ended September 30, 2022, shared profit of ¥60,976 million (¥41,372 million for the six-month period ended September 30, 2021) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Rahway, NJ, USA was included in Group headquarters’ management costs and other expenses.

(Consolidated Statement of Income)

(1) Revenue

The Group disaggregates revenue by type of goods or services. Disaggregation of revenue by reporting segment is as follows.

For the six-month period ended September 30, 2022

(Millions of yen)

	Revenue from pharmaceutical goods sales	License revenue	Other revenue	Total
Pharmaceutical business				
Japan	105,673	1,881	3,003	110,556
Americas	106,118	272	—	106,390
China	63,277	—	—	63,277
EMEA	34,952	—	—	34,952
Asia and Latin America	24,432	340	—	24,772
OTC and others	12,623	—	—	12,623
Reporting segment total	347,074	2,493	3,003	352,570
Other business (Note 1)	—	723	5,332	6,055
Total	347,074	3,216	8,335	358,626
Revenue recognized from contracts with customers	347,074	2,216	8,335	357,626
Revenue recognized from other sources (Note 2)	—	1,000	—	1,000

(Note 1) “Other business” mainly includes the license revenue and pharmaceutical ingredient business of the parent company.

(Note 2) Revenues recognized from other sources are not from contracts with customers, but from partner companies that share the risks and benefits of co-promotion activities.

For the six-month period ended September 30, 2021

(Millions of yen)

	Revenue from pharmaceutical goods sales	License revenue	Other revenue	Total
Pharmaceutical business				
Japan	98,425	1,080	4,487	103,991
Americas	75,209	15	131	75,355
China	55,263	—	—	55,263
EMEA	28,029	—	—	28,029
Asia and Latin America	24,460	156	—	24,616
OTC and others	12,149	—	—	12,149
Reporting segment total	293,535	1,250	4,618	299,403
Other business (Note 1)	—	58,945	4,004	62,949
Total	293,535	60,196	8,622	362,352

(Note 1) “Other business” mainly includes the license revenue and pharmaceutical ingredient business of the parent company. For the six-month period ended September 30, 2021, an upfront payment of ¥49,649 million from Bristol Myers Squibb under the strategic collaboration for antibody drug conjugate MORAb-202 was included in “License revenue”.

(Note 2) All revenue for the six-month period ended September 30, 2021 was recognized based on contracts with customers.

(2) Employee benefits

For the six-month period ended September 30, 2022, the Group recognized termination benefits of ¥1,404 million due to office and research laboratory closure of H3 Biomedicine Inc. (the U.S., hereinafter “H3”), a U.S. consolidated subsidiary of the Company. The details are described in “(4) Research and development expenses”.

(3) Selling, general and administrative expenses

For the six-month period ended September 30, 2022, the Group recognized shared profit of ¥60,976 million (¥41,372 million for the six-month period ended September 30, 2021) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Rahway, NJ, USA as SG&A expenses.

(4) Research and development expenses

For the six-month period ended September 30, 2022, the Company has decided to integrate its U.S. subsidiary H3 into Eisai Inc. (the U.S.). The merger is scheduled to be completed by the end of this year, and H3's research functions and assets such as drug discovery platform and investigational products will be transferred to the Group, and H3's office and research laboratory will be closed. Following this closure of office and research laboratory, the Group recognized termination benefits of ¥1,404 million as research and development expenses.

(5) Other income

For the six-month period ended September 30, 2021, the Group recognized gains on sale of non-current assets of ¥13,289 million as other income. The gains on sale of non-current assets consisted mainly of the gains arising from the divestiture of its rights for the antiepileptic agent Zonegran in Europe and other regions.

(6) Income taxes

For the six-month period ended September 30, 2022, as part of the Company's capital policy to optimize the global allocation of cash in the Company, the Company received a repayment of paid-in capital of ¥63,622 million from its consolidated U.S. subsidiary, Eisai Corporation of North America. As a result, the Company recognized losses on transferring of investments in subsidiaries for tax purposes and income taxes decreased by ¥21,287 million.

(Consolidated Statement of Cash Flows)

For the six-month period ended September 30, 2021, proceeds from sale of property, plant and equipment and intangible assets of ¥13,293 million consisted mainly of the proceeds from the divestiture of the Group's rights for the antiepileptic agent Zonegran in Europe and other regions.

(Significant Subsequent Events)

Not applicable